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UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

SURGICAL INSTRUMENT SERVICE COMPANY, INC.,

Plaintiff/ Counterclaim-Defendant

vs.

INTUITIVE SURGICAL, INC.,

Defendant/ Counterclaimant.

Case No.: 3:21-cv-03496-AMO-LB

REPLY BRIEF OF INTUITIVE SURGICAL, INC. ON CROSS-MOTIONS FOR SUMMARY JUDGMENT

Hearing To Be Renoticed
Place: Courtroom 10

Judge: The Honorable Araceli Martínez-Olguín

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

I. INTRODUCTION

The first paragraph of SIS's Reply Brief (Dkt. No. 156) ("SIS Rep.") should tell the Court all it needs to know about SIS's inability to come up with a genuine basis to oppose summary judgment. SIS begins with an extended (and far from accurate) set of disparaging descriptors for the FDA officials who for nearly a decade have consistently taken the position that modifying EndoWrists to tamper with their use counters is "remanufacturing" that requires FDA clearance under the applicable statute and regulations. SIS Rep. at 1. SIS then goes on to accuse Intuitive of ignoring "plain statutory language and FDA's public, binding pronouncements" establishing that it "was and is proper" to perform such modifications without FDA clearance. *Id.* Yet SIS's briefs identify no such "plain statutory language" or "public, binding pronouncements" from FDA that excuse EndoWrist remanufacturing from the clearance requirement. The only "public, binding pronouncements" from FDA that address that question confirm that the modification of EndoWrists *does* require clearance. More significantly, that is what *the law itself* requires, a fact that SIS asks the Court to simply ignore.

The core elements of the applicable legal regime are not disputed: Under the Food, Drug & Cosmetic Act, a Class II medical device requires appropriate measures to provide "reasonable assurance of safety and effectiveness." 21 U.S.C. § 360c(a)(1)(B). Implementation of this mandate through other statutory provisions and regulations includes a requirement that the manufacturer (or remanufacturer) of a device submit to FDA a "510(k)" submission providing extensive information about the device's design and operation, along with testing data to demonstrate its safety and effectiveness. FDA must then "clear" this 510(k) submission before hospitals may lawfully use the device on patients in a clinical setting. *See* Intuitive Opp. and Cross-Motion (Dkt. No. 137) ("CM") at 13-14.

It is also undisputed that (a) the EndoWrists used with da Vinci systems are Class II medical devices; (b) because of their unique design and construction, EndoWrists cannot be used indefinitely before they are at substantial risk of failure, endangering patient safety; and (c) the demonstration of safety and effectiveness for EndoWrists that FDA cleared encompassed use counters that disable the device after a specified number of uses. *Id.* at 3-5, 13-14. On the last of these points, SIS argues that the use counter was not FDA's idea originally and that it is not the *best* way to assure the instruments' safety and effectiveness, but SIS does not, and cannot, contest that (a) some form of protective measure

is needed, (b) use counters to implement use limits were encompassed within the 510(k) submissions that FDA cleared, and (c) FDA has subsequently treated them as a crucial elements of that clearance. *Id.*

SIS also does not dispute that "remanufacturing" a Class II medical device is unlawful absent FDA clearance and that FDA has repeatedly and consistently stated that modification of an EndoWrist to bypass its use counter constitutes "remanufacturing." *Id.* at 15. SIS disparages the authors of some FDA communications on the subject, but points to no occasion when FDA has offered a different view. And SIS has failed to present a persuasive *legal* argument for concluding that FDA is wrong. SIS cannot avoid the "remanufacturing" label FDA has applied to its activity by simply *calling* it "repair."

SIS's claims therefore fail as a matter of law. It is well established in this circuit that antitrust injury – a mandatory element of every antitrust claim – cannot be premised on the plaintiff's inability to benefit from an unlawful economic activity. SIS's Reply offers virtually no response to the showing in Intuitive's opening brief on this issue (*see* CM at 13); nor does it answer the careful legal analysis Intuitive has offered demonstrating that the remanufacture of EndoWrists is unlawful absent FDA clearance. And SIS's Lanham Act claim also fails, regardless of whether Intuitive's statements that FDA clearance was needed are viewed as truthful or merely as expressions of opinion.

SIS also has no persuasive answer on another mandatory element of its antitrust claims: proof of a substantially less restrictive alternative. *See Epic Games, Inc. v. Apple, Inc.*, 2023 WL 3050076, at *24 (9th Cir. Apr. 24, 2023). Intuitive has identified the regulatory and competitive justifications for the challenged restraints. CM at 18-22. The Ninth Circuit has made clear – including in its recent *Epic Games* decision (which SIS fails to mention) – that justifications of the kind Intuitive has presented provide a valid antitrust defense. None of SIS's accusations about the financial benefits Intuitive allegedly obtains as a result of the use limits are sufficient to undermine FDA's insistence that those use limits have so important a role in protecting patient safety that no one – not even Intuitive itself – may change them without making a *separate* safety demonstration that satisfies the agency. Under *Epic Games*, the burden is therefore on SIS to establish the existence of a substantially less restrictive alternative that is equally effective in satisfying the legitimate purposes of the challenged restraints. 2023 WL 3050076 at *24. SIS makes no meaningful effort to satisfy that standard.

SIS's challenge to the technological upgrades Intuitive has made in its X/Xi systems and EndoWrists is little short of frivolous. The Ninth Circuit has made clear that the antitrust laws cannot be used as a weapon to challenge technological improvements; to the contrary, such improvements are among the things the antitrust laws *encourage*. See CM at 22. And SIS has no answer for the fact that X/Xi systems can be used to perform surgeries that the older S/Si models cannot and are valued by customers for that reason. Nor can SIS answer Intuitive's evidence of the advantages provided by Intuitive's upgrade to wireless technology – which in turn requires tougher cybersecurity measures. Although SIS resents the fact that those measures make it more difficult to hack into Intuitive's devices, it does not – and cannot – dispute that Intuitive is justified in following FDA's directive to adopt robust cybersecurity protections.

II. ARGUMENT

In opposing Intuitive's motion for summary judgment, SIS was required to establish the existence of genuine disputes of material fact. *In re Oracle Corp. Sec. Litig.*, 627 F.3d 376, 387 (9th Cir. 2010). The dispute must be about *fact*, not about the law. *Coomes v. Edmonds Sch. Dist. No. 15*, 816 F.3d 1255, 1261-62 (9th Cir. 2016). And the fact must be *material* – not one that is "irrelevant or unnecessary," but rather one that "might affect the outcome of the suit." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Last but not least, the dispute must be *genuine* – i.e., it must arise from a significant conflict in the (admissible) evidence presented. *Elam v. Nat'l R.R. Passenger Corp.*, 220 F. Supp. 3d 996, 1000-01 (N.D. Cal. 2016) (citing *Anderson*, 477 U.S. at 248); *see also In re Oracle*, 627 F.3d at 385, 387 ("The non-moving party must do more than show there is some 'metaphysical doubt' as to the material facts at issue…." (quoting *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986))). A mere "scintilla" of evidence is insufficient. *Anderson*, 477 U.S. at 252.

In this case (unlike the parallel case brought by the hospital plaintiffs), SIS's own summary judgment motion addresses only issues also raised in Intuitive's cross-motion. SIS therefore agrees with Intuitive that there should be no dispute of material fact precluding judgment on those issues. Should, however, the Court conclude that judgment for Intuitive is barred by a disputed fact question, it cannot then go on to grant SIS's motion. That motion must be denied unless SIS can show entitlement to judgment as a matter of law based on *undisputed* facts. *Elam*, 220 F. Supp. 3d at 1000-01.

A. SIS Has Not Established the Existence of Disputed Issues of Fact That Are Material to Intuitive's Cross Motion.

Much of SIS's discussion of "facts" in the first 14 pages of its Reply focuses on assertions that are irrelevant to the issues presented in these motions.[1] Absent a showing by SIS that a factual assertion is material to these motions, the Court should simply disregard it as a red herring.

One example is SIS's contention that Intuitive has a "monopoly" in a market for "surgical robots." SIS Rep. at 1-2. Neither SIS nor Intuitive has sought summary judgment on whether Intuitive has a "monopoly" in any market within the meaning of the antitrust laws. Importantly, moreover, SIS does not claim that Intuitive either gained or maintained a "monopoly" in the alleged market for surgical robots through anticompetitive conduct. To the contrary, SIS and its witnesses claim that Intuitive has gained a dominant market position because its highly innovative da Vinci systems are popular with surgeons and hospitals and good for patients. *See, e.g.*, Cahoy Supp. Dec. Ex. 104 at 101:3-103:16; Bass Dec. Supp. Lamb (Dkt. No. 129-1) Ex. 1 ¶¶ 35-45; Lannin Dec. (Dkt. No 119-2) Ex. 1 ¶¶ 30-31, 41. This kind of success through innovation is something the antitrust laws *applaud*, not condemn. *See Verizon Commc'ns Inc. v. Law Offs. of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004).

SIS next asserts that improvements in EndoWrists have been "minimal" for the past 20 years, but again identifies no way in which this assertion would be material to the issues presented on these motions. For example, the "amount" of innovation in a particular EndoWrist has no bearing on the regulatory requirements. Nor has SIS cited evidence that could create a genuine dispute even if it *were* material. SIS's laundry list of similarities between specific aspects of S/Si EndoWrists and the later-generation X/Xi instruments falls far short of proving there are not also significant differences between them, including product improvements. The undisputed record confirms there *are* such differences, including one that SIS complains about. *See* pp. 14-15 below. It is also insufficient for SIS to claim that

[1] Points in SIS's "fact" discussion that relate to issues raised in these motions are discussed in sections of this Reply addressing those issues. Intuitive will not, however, attempt to respond to every factual assertion SIS makes that would not create a genuine dispute of *material* fact. Intuitive's failure to address a particular assertion should not be construed as agreeing that SIS's characterization of the cited evidence is accurate – it often is not – or as a waiver of evidentiary objections.

almost all relevant patents are expired. That assertion is wrong[2] and in any event irrelevant to the pending motions.

SIS also asserts that "wear and tear" and the degradation caused by intensive cleaning and sterilization processes, which limit the number of times EndoWrists can be used, are also problems for other kinds of medical instruments, and that those instruments do not have use counters. SIS Rep. at 3-4. But SIS does not (and cannot) demonstrate that EndoWrists have the same structure and components as other instruments or that they degrade in the same way, posing the same risks to patients. *See* Rosa Dec. (Dkt. No. 137-2) ¶¶ 24-27 (describing characteristics of EndoWrists that create unique risk management needs). The fact that the *different* risks associated with *different* instruments are managed in a different way has no bearing on the issues presented by these motions.[3]

Critically, SIS does not contest Intuitive's description of the Rebotix process. CM at 6-8. And that, in the end, is the *only* set of facts that is truly material to the issue on which the parties have cross-moved for summary judgment: the absence of antitrust injury as a result of SIS's lack of a legal right to pursue its remanufacturing business.

B. SIS Cannot Establish Antitrust Injury.

1. SIS Cannot Claim Antitrust Injury for Loss of Business It Had No Legal Right to Pursue.

In its opening brief on these motions, Intuitive pointed to extensive authority from the Ninth Circuit and multiple judges of this Court stating that an antitrust plaintiff has the burden of showing that it had a "legal right" to pursue the activity that is the source of its alleged antitrust injury. *See* CM at 13-14. For example, in *Modesto Irrig. Dist. v. Pac. Gas & Elec. Co.*, 309 F. Supp. 2d 1156, 1170 (N.D.

[2] SIS ignores the evidence Intuitive submitted confirming that Intuitive possesses numerous unexpired patents on innovations embodied in da Vinci systems and EndoWrists. Rosa Dec. ¶ 12. SIS cites a partial list of patents on Intuitive's website as indicating that Intuitive has only two unexpired patents on EndoWrists. SIS Rep. at 2 (citing Dkt. No. 127 at 2 n.1). Had SIS spent five minutes on the federal patent search website, *see* https://ppubs.uspto.gov/pubwebapp/static/pages/ppubsbasic.html, it would have seen that Intuitive owns hundreds of unexpired patents that describe wrist technology, dozens of which represent innovations used in EndoWrists.

[3] Equally irrelevant is SIS's argument that data on failure rates – *within the use limits* – are nearly identical for each use. *See* SIS Rep. at 4 n.1. Ensuring equal reliability for all approved uses is one of the *goals* of the sophisticated statistical analysis used to set the limits. *See* Rosa Dec. ¶¶ 28-32. SIS offers no evidence to dispute that the risk of failure increases materially once the use limit is passed.

Cal. 2004), *aff'd*, 158 F. App'x 807 (9th Cir. 2005), the court held that the plaintiff could not prove antitrust injury based on its inability to enter a market for which it lacked the necessary government clearance, thus "contravening controlling state law and attempting to derive income without attendant 'legal right.'" *Id.* The court pointed to the plaintiff's lack of any right to "unilaterally" enter the market without government clearance, and granted summary judgment for the defendant. *Id.*; *see also Snake River Valley Elec. Ass'n v. PacifiCorp*, 357 F.3d 1042, 1050 n.8 (9th Cir. 2004) (no showing of antitrust injury possible where statute did not permit the activity without state approval); *In re Canadian Import Antitrust Litig.*, 470 F.3d 785, 791-92 (8th Cir. 2006) (no antitrust injury because plaintiffs' inability to import prescription drugs was "caused by the federal statutory and regulatory scheme adopted by the [FDA]" and "not by the conduct of the defendants").

SIS makes almost no effort to address Intuitive's authorities on this point. It touches on them only in a footnote, where it merely asserts that in all of them "there was a clear violation of the law." SIS Rep. at 15 n.13. This is apparently a reference to SIS's fruitless argument that the law is not clear on whether remanufacturing of EndoWrists requires FDA clearance. But SIS identifies nothing in any of the cases that rested on the relative degree of "clarity" of the law, and the parenthetical in SIS's own cite to *Modesto Irrigation District* demonstrates the close parallel with this case: "no antitrust injury because plaintiff failed to obtain approval from a local commission to provide electricity, and therefore, was 'not a lawful competitor' of defendant." *Id.* The same situation existed here: SIS failed to obtain clearance from FDA to remanufacture EndoWrists, and therefore it was "not a lawful competitor."

The recent decision in *PharmacyChecker.com v. Nat'l Ass'n of Bds. of Pharmacy*, 2023 WL 2973038 (S.D.N.Y. Mar. 28, 2023), confirms the application of this principle to a business whose operations run afoul of FDA regulations. There, the plaintiff claimed the defendants had violated the antitrust laws by interfering with its business of facilitating consumers' ability to order drugs from foreign pharmacies. The court found the importation of prescription drugs to be illegal under the FDCA and FDA regulations; it therefore granted summary judgment because the plaintiff could not demonstrate antitrust injury for a business that was "completely or almost completely geared toward facilitating illegality." *Id.* at *20-24, *30. Notably, the court was unmoved by the plaintiffs' arguments that FDA did not enforce the regulations stringently or that their scope was unclear. *Id.* at *20-24.

Given its lack of a legal right to remanufacture EndoWrists, SIS cannot, as a matter of law, establish antitrust injury. Its arguments about Intuitive's conduct being a "proximate caus[e]" of its departure from the market (SIS Rep. at 14), as well as its overblown claim (based on the testimony of one of its own employees) of "monumental" demand (*id.* at 12) cannot create a genuine issue of material fact. No matter what impact Intuitive's actions did or did not have, SIS cannot establish antitrust injury unless it can show it had a "legal right" to engage in the business of remanufacturing EndoWrists. *Modesto Irrig. Dist.*, 309 F. Supp. 2d at 1170; *PharmacyChecker.com*, 2023 WL 2973038 at *13.

2. FDA Clearance Is Required for Remanufacture of EndoWrists.

SIS makes virtually no effort to establish that it had a legal right to remanufacture EndoWrists.[4] Apart from the bold pronouncement of its opening paragraph, SIS's Reply makes no reference to "plain statutory language" or "FDA's binding, public pronouncements" demonstrating that its business was "proper." SIS Rep. at 1. SIS cannot fill this gap by citing instead to a double hearsay report from a financial analyst who relied on interviews with persons he referred to in his report as "experts"; he admitted in his deposition that he did not even know whether a medical device requires 510(k) clearance and could not identify anyone he had spoken to other than the owner of Restore and his lawyer. *See* SIS Rep. at 8 n.4; Cahoy Supp Dec. Ex. 97 at 48:7-19, 92:7-93:4, 128:4-16, 148:16-18, 194:23-195:2.[5]

SIS's opening brief discussed the *subject* of FDA clearance but identified no statutory language or public FDA pronouncements establishing that clearance was not required here. SIS does not dispute that clearance is required for remanufacturing. And it has identified nothing in either the *statute* or the *regulations* (which SIS has never addressed at all) that can be construed as indicating that the modification of EndoWrist use counters is *not* remanufacturing. Rather, SIS's Motion pointed only to policy discussions about challenges in identifying the proper dividing line between "remanufacturing" and "repair" or "service" of devices *in general*. SIS has cited no FDA "pronouncement" – binding or

[4] SIS is defensive about the fact that Rebotix did the actual remanufacturing work and SIS was only a distributor; SIS claims it was preparing to do the work itself. *See* SIS Rep. at 12. This makes no difference to the issues presented here. SIS does not claim it had a remanufacturing process *other* than the Rebotix process; nor does it claim that it had – or tried to obtain – FDA clearance.

[5] SIS's reliance on examples in a (non-binding, unofficial) FDA "White Paper" is unavailing. *See* SIS Rep. at 9 n.5. Those examples relate to repairs of "components/parts/materials" (JVH Dec. (Dkt. No. 127-1) Ex. 45) – not to modifications that disable a critical safety feature of a cleared device.

not – saying that modification of EndoWrist use counters is even arguably not remanufacturing. There are none. To the contrary, FDA has consistently said it is remanufacturing that requires clearance, and SIS cites no evidence that FDA has "recanted" this view. SIS Rep. at 1, 9, 15. Again, there is none.

In its opening brief, Intuitive identified the regulations that define when an activity is "remanufacturing" and explained why the Rebotix process to hack into the EndoWrist use counter to bypass the use limits fits that definition. CM at 13-16. SIS has offered no contrary discussion in either of its briefs. Instead, SIS continues to rest on its original argument that it is not sufficiently *clear* that the regulations apply to modification of EndoWrists because, according to SIS (a) FDA never issued an "official" statement that applied the regulations to EndoWrists specifically, and (b) FDA took no steps to *enforce* a requirement that remanufacturers of EndoWrist use counters obtain 510(k) clearance. Even if these assertions were accurate – they are not – neither would change what the law requires, and neither would be sufficient to carry SIS's burden of demonstrating that it had a legal right to perform remanufacturing without clearance. To the contrary, compliance with the federal laws governing medical devices is mandatory regardless of whether the FDA says *anything* to confirm its application to a particular device or pursues enforcement action against anyone.

Moreover, the undisputed facts show that FDA *did* make its views known through official as well as unofficial means.[6] And SIS cannot dispute that every FDA official who has ever addressed the question has identified the activity of modifying EndoWrist use counters as "remanufacturing" that requires FDA clearance. Moreover, FDA *did* take action against Rebotix and Restore, warning both that they needed FDA clearance and should not continue operations without it. *See, e.g.*, Cahoy Dec. Exs. 23, 38 at -1256. *And both companies ceased operating*. Restore even informed FDA of its withdrawal and then hired Iconocare to develop a new process for which it recently obtained a limited FDA clearance. *Id.* Ex. 38 at -1249, Ex. 39 at 204:16-205:17, 213:19-216:23. Regardless of the reason

[6] Official actions have included an official "It has come to our attention" letter sent to Rebotix, the clearance of the Iconocare 510(k) application (which requires Iconocare to label the EndoWrists it modifies as "remanufactured"), and the creation of a separate official product code defining modified robotic surgical instruments with altered use limits as "remanufactured." *See* Cahoy Dec. (Dkt. No. 137-7) Exs. 35, 40, 41, 10 ¶¶ 150-54 & Fig. 3.

Restore and Rebotix made these choices, it is clear that FDA never needed to pursue additional enforcement action against them.

Although continuing to offer no direct discussion of the regulations themselves, SIS does seem to challenge their applicability indirectly with its argument that "FDA never substantively reviewed Intuitive's use limits, required Intuitive to have a use counter, or required the counter to self-destruct." SIS Rep. at 7 (capitalization omitted). But SIS identifies no evidence whatsoever supporting the remarkable assertion that FDA abandoned its regulatory obligation to substantively review the content of Intuitive's 510(k) applications, including the use limits and design element of a use counter that were submitted to provide the required measures to address safety and effectiveness. SIS's only citation is to an internal Intuitive email that said, *in part*, "FDA does not require nor limit the number of uses for our EW instruments." *Id.* at 8 (citing JVH Dec. Ex. 44). But SIS fails to quote the next sentence, which goes on to explain: "During the 510(k) submission process, we provide data to FDA that supports the stated number of lives for a particular instrument that we state in our labeling." FDA reviewed and cleared this showing to authorize the instruments to be used on patients. *See* Rosa Dec. ¶¶ 23, 31.[7]

That use limits are an integral part of the showing of "safety and effectiveness" that FDA relied upon in granting clearance for EndoWrists is beyond reasonable dispute. As FDA has explained, any modification of an EndoWrist to bypass the use counter causes the instrument to "no longer maintain the same safety and effectiveness profile as cleared with the original manufacturer's own submission." Cahoy Dec. Ex. 64 at -5727. In short, "if the use-life counter is reset or extended past the number of available use lives, *then the device specifications are changed*." *Id.* Ex. 31 at -0335 (emphasis added). This makes the reset process remanufacturing, which requires separate FDA clearance – not just because FDA says so (as it has consistently done) but because that is what the governing law says. *See* 21 C.F.R. §§ 807.81(a)(2), 820.3(w); *see also* 21 U.S.C. § 360(k); 21 C.F.R. §§ 807.81(a)(3), 807.20(a), 820.3(o).

The account SIS offers of Intuitive's extension of the use limits for certain X/Xi devices (SIS Rep. at 6-7) offers no support for its position. Intuitive did, to be sure, believe it was not required to provide a supplemental 510(k) submission when increasing the use limits for some X/Xi EndoWrists for

[7] SIS's attack on the sources Intuitive cited on these facts (SIS Reply at 7-8) is puzzling given that SIS presents no evidence to dispute the facts themselves but argues only about their significance.

which it already had clearance and could instead use a different regulatory process available to original manufacturers. FDA disagreed with this interpretation and required Intuitive to make a new 510(k) submission, which it promptly did. *See* Cahoy Dec. Ex. 10 ¶¶ 259-65; Cahoy Supp. Dec. Ex. 98. The only material fact emerging from this episode is that FDA is adamant that *no one* – not even Intuitive – can change the use limits for an EndoWrist without separate 510(k) clearance.[8]

Nor can SIS find support in the timing of Intuitive's public statement confirming that its contracts do not prohibit use of FDA-cleared remanufactured instruments. *See* SIS Rep. at 12. This statement was made shortly after Iconocare obtained its first clearance, and it is undisputed that no one had clearance before that. Intuitive's contracts allow use of instruments that are "approved" (*see* Cahoy Dec. Ex. 11 at -5488), and SIS cites no evidence that Intuitive ever told a customer it could not use FDA-cleared remanufactured instruments should they become available. SIS has no evidence that Intuitive did anything to impede anyone in seeking FDA clearance – which SIS and its partner Rebotix were committed to avoiding – or to prevent anyone from operating if clearance was obtained.

SIS's Reply (at 9-10) offers one new argument that *might* be directed at the legal standard for defining "remanufacturing"; if so, it is easily rejected. SIS argues that Rebotix did not act inconsistently in filing a 510(k) application (which FDA rejected) and then later taking the position that it did not need clearance when modifying EndoWrists that continued to be owned by the original purchasers. SIS argues that Rebotix's application was based on the fact that it originally planned to change the device "packaging." SIS asserts that it did not change the "device package" or "engage in commercial distribution of EndoWrists." *Id.* The first of these is a red herring; the latter attempts to slip in, with no explanation, a contention that is directly contradicted by, among other things, binding case law.

A device in "commercial distribution" must have FDA clearance. 21 C.F.R. § 807.81(a). "Commercial distribution" is "any distribution of a device intended for human use which is held or

[8] SIS offers apples-and-oranges statistics about post-sale failure rates for S/Si and X/Xi EndoWrists as if they had a material bearing on this question. SIS Rep. at 6-7. Although Intuitive tracks post-sale failure rates and follows up, where appropriate, to address issues, Rosa Dec. ¶ 40-42, that is not the data that FDA considers in granting clearance. *See id.* ¶¶ 28-31 (describing testing and clearance process). SIS identifies no evidence that a raw statistic on post-sale failure rates, with no control for other factors (*see, e.g.*, JVH Dec. (Dkt. No. 156-1) Ex. 41 at -7520-21), is material to any issues on these motions.

offered for sale." 21 C.F.R. § 807.3(b). Rebotix's "loophole" argument was that the modification of a device can never satisfy this definition unless the device is *sold* after it is modified. FDA was not moved by this argument,[9] and the Ninth Circuit rejected it in *United States v. Kaplan*, 836 F.3d 1199, 1208-11 (9th Cir. 2016).

In *Kaplan* – which SIS does not even mention in its Reply – the Ninth Circuit upheld the criminal conviction of a doctor for violating a parallel provision of the FDCA prohibiting "adulteration" of products that are "held or offered for sale" (the same language on which Rebotix relied). *Id.* at 1211-12. The doctor was taking a medical device that was cleared for only one use and, after attempting to clean it, using it in additional procedures. In appealing his conviction, he argued that he did not violate the statute because he was not selling devices but was instead re-using devices he already owned. The Ninth Circuit disagreed, holding that the phrase "held or offered for sale" is not limited to a "sale in the strict sense." *Id.* at 1209. Instead, it covers a "commercial actor in a commercial setting, using a commercial product" to treat patients. *Id.* at 1210 ("[P]atients who paid Kaplan for the medical services he performed were also paying for the cost of products used in the course of treatment, including biopsies, and … the patients were therefore the ultimate consumers of the guides."). The court also cited the general purpose of the FDCA in protecting health and safety. *Id.* ("This interpretation of 'held for sale' comports with Congress's intent that the FDCA be interpreted broadly."). Similarly here, where remanufactured EndoWrists were to be used on patients, the need for 510(k) clearance could not be avoided by claiming the remanufactured instruments were not separately "sold."

C. SIS Fails to Demonstrate a Substantially Less Restrictive Alternative that Satisfies the Legitimate Justifications Intuitive Has Established.

SIS's antitrust claims also fail as a matter of law for an independent reason: SIS is unable to prove the existence of a substantially less restrictive alternative to the challenged restraints that would achieve the same pro-competitive and regulatory compliance purposes. Much of SIS's discussion of this subject is consumed by an argument that Intuitive, in using the term "reasonable" in its discussion of this issue, is asking the Court to apply a special standard that differs from existing law. This is an odd

[9] FDA repeatedly warned Rebotix that it needed clearance, including in response to this same argument. *See* Cahoy Dec. Ex. 31 at -0335. FDA made clear long ago that change in ownership is not pertinent to whether 510(k) clearance is needed. *See* 63 Fed. Reg. 67076, 67077 (Dec. 4, 1998).

argument, given that the standard antitrust test has long been referred to as the "rule of reason." *See, e.g., Fed. Trade Comm'n v. Qualcomm, Inc.*, 969 F.3d 974, 988-89 (9th Cir. 2020). In any event, lest there be any doubt, Intuitive relies on *existing* law from the Supreme Court and Ninth Circuit and seeks nothing different. SIS's other arguments have no greater merit.

To begin with, SIS offers no answer to the fundamental problem that it cannot rest an *antitrust* claim on the mere existence of use limits for EndoWrists. An antitrust claim must rest on a showing of injury *to competition*, and the *only* competition that SIS claims it wanted to pursue consisted of modifying Intuitive's EndoWrists to *reset the use counters*. If there had been no use counters (which SIS colorfully describes as "self-destruct" mechanisms), there would have been nothing for SIS to "reset." SIS identifies no genuine "repair" service that it was stymied from providing. To the contrary, SIS has stressed the fact that the Rebotix process began with *discarding* broken instruments and only offered reset "service" on those that did not need real repair. *See* Dkt. No. 148 at 11. Customers almost never have any need for genuine "repair" of EndoWrists, as Intuitive maintains a liberal return policy that allows customers to freely return any malfunctioning instruments to Intuitive. *See* Rosa Dec. ¶ 40.

Even if SIS's attacks on the use limits had legal significance, SIS has no answer to the fact that the limits, and the use counter that implements them, were cleared by FDA as critical elements of the showing of "safety and effectiveness" that allows EndoWrists to be sold and used on patients – elements so important that FDA will not allow *anyone* to change them without new testing and FDA clearance.

SIS's statement that "[t]here is no 'safety' exemption from the antitrust laws" (SIS Rep. at 17) is a pure straw-man argument. As the Ninth Circuit explained in *Epic Games*, the cases SIS cites (*id.* at 17 n.16), which were also cited by *Epic*, stand only for the proposition that a defendant may not claim "that *competition itself* is ill-suited to a certain market or industry." 2023 WL 3050076 at *22. But courts regularly accept the justifications that a restraint promoting safety makes the defendant's product more competitively attractive to consumers or satisfies regulatory requirements. *Id.* at *21 ("Antitrust law assumes that competition best allocates resources by allowing firms to compete on all elements of a bargain—quality, service, safety, and durability—and not just the immediate cost." (internal marks and citation omitted)); *Phonetele, Inc. v. AT&T Co.*, 664 F.2d 716, 737-78 (9th Cir. 1981) (recognizing defense based on "imperatives recognized as legitimate by the regulatory authority").

The use limits for EndoWrists, which were cleared as satisfying regulatory requirements and which promote the safety of the da Vinci system as an alternative to other modes of surgery, satisfy both of these independent tests. They were presented to and cleared by FDA as measures that would meet the statutory requirement of controls to establish "safety and effectiveness." And there is no genuine dispute that they serve that purpose, even if SIS argues that a different measure would be better.

SIS's extensive and sometimes colorful arguments about Intuitive's pursuit of "profits" cannot create a genuine dispute of material fact on this point. A restraint that satisfies a legitimate pro-competitive purpose cannot be challenged under the antitrust laws merely because it enhances, or even maximizes, the defendant's profits. *See U.S. Football League v. Nat'l Football League*, 842 F.2d 1335, 1360-61 (2d Cir. 1988). Intuitive's products can only be profitable if they are in demand, and numerous witnesses tout the superiority of the da Vinci system in comparison to other surgical modes based on the superior patient outcomes it offers. *See, e.g.*, Cahoy Supp. Dec. Ex. 99 at 15:6-16:6; *id.* Ex. 102 at 11:7-25; *see also* Smith Dec. (Dkt. No. 137-5) Ex. 1 ¶¶ 84-85, 135-55. SIS does not – and cannot – dispute that the safety of a medical device is important to its competitive value.

The burden therefore shifts to SIS to demonstrate the existence of a substantially less restrictive alternative to achieve the benefits realized by EndoWrist use counters. *Epic Games*, 2023 WL 3050076 at *24. And "[t]o qualify as 'substantially less restrictive,' an alternative means must be virtually as effective in serving the defendant's procompetitive purposes … without significantly increased cost." *Id.* (internal marks and citations omitted). In *Epic Games*, the court found the plaintiff's showing on its proposed alternatives, which were far more concrete than those presented by SIS here, nonetheless lacked details necessary to establish the necessary equivalence of effectiveness and cost. *Id.* at *24-25.

SIS's Reply offers no attempt to defend its only tentative stab at a less restrictive alternative – the hypothetical suggestion from its engineering expert that it might be possible to design a different kind of use counter that relies on different data inputs to determine whether a particular instrument has reached its safe limit. *See* CM at 21. SIS has no evidence that any such hypothetical alternative design would actually be "less restrictive" (i.e., would, on average, allow instruments to be used longer). Nor, since SIS has no *specific* alternative to offer, does it have evidence that it would be equally effective in managing risk or have equivalent cost.

SIS's characterization of Intuitive's efforts to prevent circumvention of FDA-cleared limits on EndoWrists as the "510(k) police" (SIS Rep. at 17) ignores the fact that all of the challenged conduct was specifically directed at ensuring that the instruments used with these highly regulated systems are in compliance with regulatory requirements, including the FDA-cleared use limits. EndoWrists are *part of* the da Vinci system; and if they are used outside their specifications, the whole system is outside specifications. It can surely have been no antitrust violation for Intuitive to inform customers of its concern that the remanufacture of instruments without FDA clearance was unsafe and unlawful. Those communications, and the contracts requiring only approved instruments to be used with a da Vinci system, implemented Intuitive's *ongoing* responsibility to ensure that the systems to which remanufactured instruments would be attached remained within approved safety parameters. *See* Rosa Dec. ¶ 29-30; *see also, e.g.*, 21 C.F.R. §§ 820.90, 820.100, 820.160, 820.198, 830.10, 830.50. As the Ninth Circuit has cautioned, the "the proper role of antitrust courts is to accommodate the peculiar circumstances under which regulated industries operate." *Phonotele*, 664 F.2d at 742.

D. SIS Has Not Established a Genuine Dispute of Material Fact About Whether the X/Xi Systems and EndoWrists Include Improvements or Were Accepted by Customers Without Coercion.

SIS does not contest that antitrust challenges to product design changes fail if (1) the design change was an improvement, and (2) customers were not coerced to accept it. *Allied Orthopedic Appliances, Inc. v. Tyco Health Care Grp. LP*, 592 F.3d 991, 999, 1000 (9th Cir. 2010). SIS offers no evidence to dispute Intuitive's showing that the X/Xi system offers improved capabilities over the S/Si. Multiple witnesses testified that the X/Xi can be used for surgical procedures that would be infeasible to perform with the S/Si. *See* CM at 3; *see also* Cahoy Supp. Dec. Ex. 99 at 17:7-19:4; *id.* Ex. 102 at 12:21-13:16; *id.* Ex. 101 at 18:16-19:4. SIS cannot dispute that this is an improvement.

SIS also focuses on a specific change in the X/Xi instruments – upgrading from a wired Dallas chip to a wireless RFID chip with more memory and other features, complete with encryption to protect against cybersecurity threats. SIS does not dispute that encryption of a wireless chip to mitigate against cybersecurity threats is consistent with FDA cybersecurity guidelines. *See* CM at 11-12. Rather, SIS contends that Intuitive should not have used a wireless chip at all and then would not need to encrypt it. SIS Rep. at 13 n.11. But SIS offers no evidence to create a genuine dispute over Intuitive's showing that

the change to wireless allowed improved consistency and reliability – among other things, the pins in the S/Si chip can be damaged when repeatedly connecting and disconnecting from the system (*see* Cahoy Dec. Ex. 85 ¶ 58-59) – and that the wireless chip has more memory. *See* CM at 24. SIS's reverse engineering expert confirmed that both "consistency on detection of electrical contacts" and "memory parameters" are important design considerations. Cahoy Dec. Ex. 86 at 97:5-98:24. SIS does not identify any admissible evidence that these were *not* improvements; it merely speculates that there were also other reasons for the change. That is not enough to create a disputed fact issue – the law does not require demonstrated improvements to be the *only* reason for a technological change. *See Allied Orthopedic*, 592 F.3d at 1000-01 (holding that a product improvement "is 'necessarily tolerated by the antitrust laws'" and that "[t]here is no room in this analysis for balancing the benefits or worth of a product improvement against its anticompetitive effects" (citations omitted)).

No dispute of material fact exists on the coercion element either. *See Allied Orthopedic*, 592 F.3d at 1000. SIS asserts in a footnote that there is a "dispute" about whether Intuitive "has taken steps" to force customers to switch from earlier generation S/Si systems. SIS Rep. at 19 n.18. But it cites no evidence that any customer was in fact coerced. To the contrary, the testimony of hospital witnesses confirms that they moved to X/Xi systems because of their improved technology and functionality. *See* CM at 22-23. Moreover, Intuitive committed to continuing to support the older systems for a full *decade* after the new versions were introduced; SIS cites no law requiring even that much.

E. SIS's Lanham Act Claim Fails As a Matter of Law.

The one short paragraph SIS devotes in its Reply to its Lanham Act claim fails to address the primary points raised in Intuitive's Cross-Motion: that Intuitive's statement that FDA clearance was required was true, but that if SIS were right that this legal question is unclear, it would be treated under the Lanham Act as a mere opinion, which is not actionable under that statute. *See* CM at 25. SIS's references to "misleading" statements (SIS Rep. at 20) fail to identify any statements of *fact* that were misleading, much less to explain *how* they were misleading.

III. CONCLUSION

Intuitive's motion for summary judgment should be granted; SIS's motion should be denied.

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